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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,631	09/27/2001	Carl Johan Friddle	LEX-0241-USA	2486

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THE WOODLANDS, TX 77381-1160

EXAMINER

NASHED, NASHAAT T

ART UNIT PAPER NUMBER

1652

DATE MAILED: 08/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/965,631

Applicant(s)

FRIDDLE ET AL.

Examiner

Nashaat T. Nashed, Ph. D.

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 09 July 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.Claim(s) objected to: None.Claim(s) rejected: 1-3, 6, 8, and 9.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____



Nashaat T. Nashed, Ph. D.
Primary Examiner
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Claims 1-3, 6, 8, and 9 are pending and under consideration.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 6, 8, and 9 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility, for the reasons set forth in the prior Office actions mailed June 28, 2003, and February 5, 2004.

In response to the above rejections, Applicants requested the reconsideration of their previous arguments filed November 28, 2003 and expanded some of their previous arguments

Applicants' arguments filed 7/9/04 have been fully considered but they are not deemed to be persuasive. The arguments filed November 28, 2003 have been fully considered and addressed in the final Office action, mailed February 5, 2004. Applicants cite *In re Brana* to support their utility for the use of the nucleic acid and/or the amino acid sequence for treating or diagnosing diseases, see page 5 of applicants' response. The examiner does not find the recitation of *In re Brana* relevant in this particular case because the applicants have not asserted a specific disease to be treated or diagnosed. Thus, the examiner has not confused the requirements of obtaining a patent and government approval for marketing a particular drug for human consumption. Unlike enablement rejections, which can be overcome by a post priority date publication, utility rejection can't be overcome by a post priority date publication because the claimed invention must have an asserted substantial or a well-established utility as of the priority date of the application. GenBank accession number NP-620686.1, which has 100% sequence identity to SEQ ID NO: 4 has been annotated by a third as encoding a disintegrin-like protein with thrombospondin type 1 motif, see page 6 of applicants' response, but the annotation does not provide any utility, let alone prior to the priority date of the application. Porter *et al.* is irrelevant to this application because it is published 2004, well after the earliest priority date of the instant application. As for example 10 of PTO's revised Guidelines training material pages 53-55, unlike proteases, DNA ligases are not known to have substrate specificity, and therefore, the name itself indicates a specific and substantial utility, i. e., joining two pieces of DNA which is a known chemical function of all DNA-ligases.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6, 8, and 9 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth in the prior Office action, mailed June 28, 2003 and February 5, 2004.

In response to the above rejection, applicants argue that the phrase "highly stringent conditions" is defined in the specification on page 5, lines 1-8, which the examiner acknowledge. They further argue that the Board has recently settled the issue, without giving any reference to a particular case.

Applicants' arguments filed 7/9/04 have been fully considered but they are not deemed to be persuasive. The test of definiteness of a claim containing a defined phrase such as "highly stringent conditions" is to insert the definition into the claim, and determine whether the claim is definite or not. In the instant situation, the claim will include "e. g.," which mean for example. The phrase "for example" is indefinite and therefore, the claim as a whole is indefinite. The examiner is not aware of any recent Board binding decision, which settled this issue. Consequently, the examiner has no further comment on the Board decision until applicants provide a copy of said decision.

No claim is allowed.

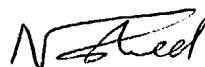
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax

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phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Primary Examiner
Art Unit 1652